JAN 8 2002

Roche Acetaminophen Assay

510(k) Summary

K013757

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000

Contact Person: Mike Flis

Date Prepared: November 9, 2001

2) Device name

Roche Acetaminophen

3) Predicate device

We claim substantial equivalence to the COBAS INTEGRA Acetaminophen Assay.

4) Device Description

The Roche Acetaminophen assay contains an in vitro diagnostic reagent system indicated for the quantitative determination of toxic levels of acetaminophen in human serum or plasma on automated clinical chemistry analyzers. The proposed labeling indicates the Roche/Hitachi 911, 912, 917, and Modular P analyzers can be used with the Roche Acetaminophen reagent kits.

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510(k) Summary, Continued

5) Intended use

For the quantitative determination of toxic levels of acetaminophen in human serum or plasma on automated clinical chemistry analyzers.

6) Comparison to predicate device

The Roche COBAS INTEGRA Acetaminophen was evaluated for several performance characteristics, including precision, lower detection limit, method comparison, specificity, and interfering substances. All of the evaluation studies gave acceptable results compared to the predicate device. These experiments provide evidence that the Roche Acetaminophen Assay is substantially equivalent to the currently marketed Roche COBAS INTEGRA Acetaminophen Assay. The following table presents the precision and method comparison results.

Roche Acetaminophen				**Roche COBAS INTEGRA Acetaminophen, (Predicate)**		
Versus Roche COBAS INTEGRA Acetaminophen assay on the COBAS Integra 700 N = 150 Y = -0.31 + 0.987x R =0.999 Range = 1.2 to 160.6 µg/mL				Versus Abbott TDx Acetaminophen assay N=87 Y=1.047x – 6.689 R=0.984 Range = 0-234.7µg/mL		
Precision:	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Mean (µg/mL)	7.9	34.83	102.13	9.9	32.9	97.4
CV% (within run)	5.6	1.2	0.5	5.8	0.9	0.7
CV% (day to day)	5.7	1.0	1.4	3.7	4.0	4.3
CV% (total)	5.7	1.5	1.4	7.5	4.4	4.9

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Mike Flis
Regulatory Affairs Principal
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

JAN 8 2002

Re: k013757
Trade/Device Name: Roche Acetaminophen Assay
Regulation Number: 21 CFR 862.3030
Regulation Name: Acetaminophen test system
Regulatory Class: Class II
Product Code: LDP
Dated: November 9, 2001
Received: November 13, 2001

Dear Mr. Flis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Roche Diagnostics Corporation

510(k) Number (if known): K013757
Device Name: Roche Acetaminophen Assay
Indications for Use:

For the quantitative determination of toxic levels of acetaminophen in human serum or plasma on automated clinical chemistry analyzers. Measurements obtained by this device are used in the diagnosis and treatment of acetaminophen overdose.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013757

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)